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**TELEFAX**

**Date:** January 4, 2005 **Total pages:** 13 including cover  
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**From:** Rivka Monheit **Telephone:** 404-879-2152 **Telefax:** (404) 879-2160  
**Our Docket No.** ACU 109 CIP **Client/Matter No.** 077586/00027  
**Your Docket No.**

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**MESSAGE:****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Applicant:** Julie Straub, David Altreuter, Howard Bernstein, Donald E. Chickering  
III, Sarwat Khattak, and Greg Randall  
**Serial No.:** 10/053,929 **Art Unit:** 1617  
**Filed:** January 22, 2002 **Examiner:** Edward J. Webman  
**For:** *POROUS DRUG MATRICES AND METHODS OF MANUFACTURE  
THEREOF*

**AMENDMENT AND RESPONSE  
AND TERMINAL DISCLAIMER**

45053394.1

ACU 109 CIP  
077586/00027

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b>  <small>(to be used for all correspondence after initial filing)</small>	Application Number	10/053,929	
	Filing Date	January 22, 2002	
	First Named Inventor	Straub et al.	
	Art Unit	1617	
	Examiner Name	Edward J. Webman	
Total Number of Pages in This Submission	12	Attorney Docket Number	ACU 109 CIP

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input checked="" type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Two Statements Under 37 CFR 3.73(b)
Remarks _____		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Pabst Patent Group LLP		
Signature	<i>Rivka D. Monheit</i>		
Printed name	Rivka D. Monheit		
Date	January 4, 2005	Reg. No.	48,731

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I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:			
Signature	<i>Carla Stone</i>		
Typed or printed name	Carla Stone	Date	January 4, 2005

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PTO/SB/17 (12-04)

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Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). <b>FEE TRANSMITTAL</b> <b>For FY 2005</b>		<b>Complete if Known</b>	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Application Number	10/053,929
		Filing Date	January 22, 2002
		First Named Inventor	Straub et al.
		Examiner Name	Edward J. Webman
		Art Unit	1617
<b>TOTAL AMOUNT OF PAYMENT</b> (\$ 65.00)		Attorney Docket No.	ACU 109 CIP

**METHOD OF PAYMENT** (check all that apply)

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**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

<b>Total Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>	<b>Multiple Dependent Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>
6	- 33 or HP = 0	x	=			
HP = highest number of total claims paid for, if greater than 20						
<b>Indep. Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>			
1	- 3 or HP = 0	x	=			
HP = highest number of independent claims paid for, if greater than 3						

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

<b>Total Sheets</b>	<b>Extra Sheets</b>	<b>Number of each additional 50 or fraction thereof</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>
	- 100 =	/ 50 =	(round up to a whole number) x	=

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other: Terminal Disclaimer

Fees Paid (\$)

\$65.00

<b>SUBMITTED BY</b>			
Signature	<i>Rivka D. Monheit</i>	Registration No. (Attorney/Agent)	48,731
Name (Print/Type)	Rivka D. Monheit	Telephone	(404) 879-2152
		Date	January 4, 2005

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**Examiner:** Edward J. Webman

**For:** *POROUS DRUG MATRICES AND METHODS OF MANUFACTURE THEREOF*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**AMENDMENT AND RESPONSE**

Sir:

Responsive to the Office Action mailed on October 7, 2004, please amend the application as follows. Submitted with this Amendment and Response is a Terminal Disclaimer and two Statements Under 37 C.F.R. §3.73(b). The Commissioner is hereby authorized to charge \$65.00, the Terminal Disclaimer fee for a small entity, to Deposit Account No. 50-3129. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

U.S.S.N. 10/053,929

Filed: January 22, 2002

**AMENDMENT AND RESPONSE TO OFFICE ACTION****Amendment**

Claims 1-15. (Canceled)

16. (Currently amended) A method for making a pharmaceutical composition comprising ~~comprising~~ a porous matrix formed of at least one hydrophilic or hydrophobic excipient and microparticles of a drug, wherein the microparticles have a mean diameter between about 0.1 and 5  $\mu\text{m}$  and a total surface area greater than about 0.5  $\text{m}^2/\text{mL}$ , and wherein the dry porous matrix is in a dry powder form having a TAP density less than or equal to 1.0  $\text{g/mL}$  and having a total surface area of greater than or equal to 0.2  $\text{m}^2/\text{g}$ , comprising

(a) dissolving a drug in a volatile solvent to form a drug solution,

(b) combining at least one volatile solid pore forming agent with the drug solution to form an emulsion, suspension, or second solution,

(c) incorporating at least one excipient into the emulsion, suspension, or second solution, wherein the excipient is selected from the group consisting of hydrophobic and hydrophilic excipients which enhance dissolution rate, which stabilize drug in amorphous form by preventing crystallization, and which stabilize drug in crystalline form by inhibiting crystal growth, and

(d) removing the volatile solvent and pore forming agent from the emulsion, suspension, or second solution to yield the porous matrix of drug and excipient.

17. (Original) The method of claim 16 wherein step (d) is conducted using a process selected from spray drying, evaporation, fluid bed drying, lyophilization, vacuum drying, or a combination thereof.

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Filed: January 22, 2002

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

18. (Original) The method of claim 16 wherein the excipients are selected from the group consisting of polymers, amino acids, wetting agents, sugars, preservatives, pegylated excipients, tonicity agents, and combinations thereof.

19. (Original) The method of claim 16 wherein the matrix comprises between 1 and 95% drug by weight in combination with at least one hydrophilic or hydrophobic excipient which enhances the rate of drug dissolution, stabilizes the drug in crystalline form by inhibiting crystal growth or stabilizes the drug in amorphous form by preventing crystallization.

20. (Original) The method of claim 16 wherein the pore forming agent is a volatile salt.

21. (Original) The method of claim 20 wherein the volatile salt is selected from the group consisting of ammonium bicarbonate, ammonium acetate, ammonium chloride, ammonium benzoate, and mixtures thereof.

Claims 22-33. (Canceled)